

SDA 40B- alcohol solution
Mann Lake Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Sani-Effect Gel Hand sanitizer Fresh Scent with Viatmin E and Aloe Vera

This is a hand sanitizer.

Active Ingredient(s)

Alcohol 70% v/v. Purpose Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame.

Di not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control center right away.

Directions

- Place enough product on the hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

glycerin, triethanolamine, carbomer, ethyl acetate, vitamin E, aloe vera, fragrance, purified water USP

8019-0116-1



| | |
|--|------------------------------|
| Drug Facts | |
| Active Ingredient(s) Alcohol 70% v/v | Purpose Antiseptic |
| Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| Warnings For external use only. Flammable. Keep away from heat or flame | |
| Do not use • In children less than 2 months of age • on open skin wounds | |
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| Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients purified water, glycerin, acrylate copolymer, tocopheryl acetate, aloe vera, fragrance, ethyle acetate, triethanolamine | |

Manufactured by:
Mann Lake Ltd.
501 1st Street S.
Hackensack, MN 56452

HS-116 | MLL 10-198 Rev 08/03/20



1 Gallon (128 oz)

80194-116-2



GEL
HAND SANITIZER FRESH SCENT

70% Alcohol |  Proudly Made in America

+ Vitamin E & Aloe For Hydrated & Clean Hands

GEL HAND SANITIZER

| Drug Facts | |
|--|------------|
| Active Ingredient(s) | Purpose |
| Alcohol 70% v/v | Antiseptic |
| Use(s) | |
| Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| Warnings | |
| For external use only. Flammable. Keep away from heat or flame | |
| Do not use | |
| <ul style="list-style-type: none"> in children less than 2 months of age on open skin wounds | |
| When using this product | |
| keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. | |
| Stop use and ask a doctor | |
| if irritation or rash occurs. These may be signs of a serious condition. | |
| Keep out of reach of children. | |
| If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions | |
| <ul style="list-style-type: none"> Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information | |
| <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients | |
| purified water, glycerin, acrylate copolymer, tocopheryl acetate, aloe vera, fragrance, ethyle acetate, triethanolamine | |



Manufactured by:
 Mann Lake Ltd.
 501 1st Street S.
 Hackensack, MN 56452
 HS-115 | MLL 10-197
 Rev 08/03/20

8 FL OZ (236 mL)

SDA 40B

alcohol solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80194-0116 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 L in 100 L |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------|---------------|
| WATER (UNII: 059QF0KO0R) | 30 L in 100 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:80194-0116-1 | 3.78 L in 1 PACKAGE; Type 0: Not a Combination Product | 08/19/2020 | |
| 2 | NDC:80194-0116-2 | 0.236 L in 1 PACKAGE; Type 0: Not a Combination Product | 08/19/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 08/19/2020 | |

Labeler - Mann Lake Ltd (121181846)**Registrant** - Mann Lake LTD (121181846)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---------------|---------|-----------|-------------------------|
| Mann Lake Ltd | | 121181846 | manufacture(80194-0116) |

Revised: 8/2022

Mann Lake Ltd